Supreme Court, U.S.
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No. _____

In The

Supreme Court of the United States

October Term, 1997

VICTOR TORBECK, WBI, formerly known as WORLDWIDE BIOLOGICALS, INC., and NBI, formerly known as NASHVILLE BIOLOGICALS, INC.,

Petitioners,

versus

THOMAS S. BOZZO, RONALD CHESEMORE, GARY DYKSTRA, DAVID KESSLER, GERALD V. QUINNAN, and KATHRYN ZOON, Ph.D,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fourth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED FOR REVIEW

Are federal officials entitled to qualified immunity upon a FRCP 12(b)(6) motion to dismiss where:

1. They take no action to provide an FDA licensed business with a hearing for almost two years after shutting down the business for alleged violations of FDA regulations; and

2. They were well aware of the license holder's right to a prompt post-deprivation hearing; and

3. They ultimately secured the surrender of the license by denying the licenseholder a hearing and securing his guilty plea to charges completely unrelated to those allegations by which they had sought to justify their shutting down the licenseholder's business in the first place?

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OPINIONS AND ORDERS BELOW

The Opinion of the Court of Appeals for the Fourth Circuit sought to be reviewed may be found at pages 1a to 9a of the Appendix to this Brief. The opinion was not published in any official reporter.

The Order of the United States Court of Appeals for the Fourth Circuit denying the Plaintiffs' Petition for Rehearing may be found at pages 14a and 15a of the Appendix to this Brief.

The Opinion of the United States District Court for the District of Maryland may be found at pages 10a to 12a of the Appendix to this Brief. The opinion was not published in any official reporter.

The Order of the United States District Court for the District of Maryland dismissing the Plaintiffs' Amended Complaint may be found at page 13a of the appendix to this Brief.

JURISDICTION OF THE COURT

The Opinion of the United States Court of Appeals for the Fourth Circuit was entered on August 29, 1997, affirming the FRCP 12(b)(6) dismissal entered by the District Court on June 4, 1996.

The Order of the United States Court of Appeals for the Fourth Circuit denying the Plaintiffs' Petition for Rehearing was entered on October 27, 1997. (See Appendix as indicated above).

The jurisdiction of this Court is invoked pursuant to 28 United States Code §1254(1).

CONSTITUTIONAL PROVISION AND ADMINISTRATIVE REGULATION INVOLVED

Amendment V, Constitution of the United States

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law, nor shall private property be taken for public use, without just compensation.

STATEMENT OF THE CASE

This Petition arises from a lawsuit brought by Victor Torbeck, WBI, formerly known as Worldwide Biologicals, Inc., and NBI, formerly known as Nashville Biologicals, Inc., against David Kessler, Gerald V. Quinnan, Jr., Kathryn Zoon, Ronald Chesemore, Gary Dykstra, and Thomas S. Bozzo.

Torbeck and his wife, Carol, reside in Cincinnati, Ohio and are the sole shareholders of the corporate Plaintiffs, both of which are Ohio corporations.

NBI was originally organized to do business in April, 1989; WBI in April, 1990. NBI operated a plasmapharesis (plasma donor and collection center) in Nashville, Tennessee under United States Food and Drug Administration (hereinafter FDA) license #1082-001. WBI operated a similar center in Fayetteville, North Carolina under FDA license #0832-003 (Record of the District Court, #13, Amended Verified Complaint; This Brief, pp. 16a-29a; hereinafter Amd. Complaint with appropriate paragraph numbers; as to the facts just cited ¶¶1-3, 11, 29, 31; Appendix, pp. 16a-17a, 18a, 22a).

At the time of the wrongs complained of in this lawsuit, the Defendants held the following positions with the FDA:

David Kessler, Commissioner;

Gerald V. Quinnan and Kathryn Zoon, Director of the Center for Biologic and Evaluation Research;

Ronald Chesemore, Associate Commissioner for Regulatory Affairs;

Gary Dykstra, Chesemore's assistant; and

Thomas S. Bozzo, Director of the Office of Compliance (Amd. Complaint, ¶¶4-8; p. 17a).

On May 15, 1992, the Defendant Thomas Bozzo informed Victor Torbeck that WBI's Fayetteville Center could no longer collect or store source plasma (Amd. Complaint ¶13; p. 18a). Torbeck then sought to persuade the FDA to abate this action (*Id.*, ¶14; pp. 18a-19a). On June 15, 1992, the Defendant Kathryn Zoon wrote Torbeck that the FDA had denied his request for abatement and

that the FDA intended to revoke WBI's license #0832-003 (*Id.*, ¶15; p. 19a).

Included in Dr. Zoon's letter of June 15, 1992 was a statement that the FDA intended to issue a notice of an opportunity for WBI to receive a hearing on the revocation of WBI's license and that Mr. Torbeck's failure to waive such a hearing would be taken as an indication that he wanted the hearing, which would be held in accordance with 21 Code of Federal Regulations §12.21(b) [*Id.*, ¶15; p. 19a]. Within two weeks, FDA official Nancy Murphy sent a letter to Torbeck acknowledging the FDA's understanding that WBI wanted to have a hearing on the FDA's proposed revocation of its license to operate the Fayetteville Center (*Id.*, ¶17; p. 19a).

As of May 15, 1992, however, the FDA had put WBI's Fayetteville plasma center out of business (*Id.*, ¶18; p. 20a). During the following months WBI had no choice but to destroy much of its inventory. In September, 1992, the FDA confiscated what was left of WBI's inventory (*Id.*, ¶18-19; p. 20a).

Torbeck sought surreptiously to salvage something from the destruction of his business, and sold three valuable pure bottles of WBI's inventory after the FDA had ordered him not to do so. As a result of this conduct, Torbeck on April 29, 1997 pleaded guilty to three charges of violating the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-309, and one count of making a false statement pursuant to 18 U.S.C. §1001 (Record of the District Court, #17, Motion to Dismiss, P. 10).

There was no legal connection between these criminal charges and the administrative allegations upon

which the Defendants based their shutting down of WBI's Fayetteville center. Neither the Defendants to this action nor any other FDA officials over sought to link these two situations in any formal manner.

A condition of Torbeck's plea, upon which the government insisted as a condition of not opposing probation for him, was that Torbeck surrender WBI's license #0832-003, which of course Torbeck did.

During the entire period from May 15, 1992, until April 29, 1994, neither the Defendant Kessler nor any of his minions provided WBI with any sort of hearing on the propriety of their having put WBI out of business in Fayetteville. In fact, they never so much as got around to setting a date certain for a hearing. The closest WBI came to receiving a hearing was when Dr. Zoon published a notice of an "opportunity for a hearing" on the FDA's "proposal" to revoke license #0832-003 in the Federal Register on March 22, 1993 (Amd. Complaint, ¶¶17-24; pp. 19a-21a).

This "notice" and the letters to Torbeck from Zoon of June 15, 1992, and Nancy Murphy of June 29, 1992, respectively, were the sum and substance of the "due process" that the Defendants provided to WBI, the business of which was totally destroyed between May of 1992 and April of 1994.

In no manner did WBI or Torbeck waive their right to a hearing during this time. They sought documents from the Defendants several times to assist them in their efforts to get the Fayetteville Center re-opened (Amd. Complaint, ¶¶20, 21, 22; p. 20a). Furthermore Torbeck demanded a hearing for WBI by letters dated March 19,

1993, April 12, 1993, and May 20, 1993 (*Id.*, ¶¶22, 23, 26; pp. 20a-21a).

These pleas, of course, were not heeded.

After the government instituted criminal charges against Torbeck, the Defendants' denial of the due process rights of Torbeck and WBI took on positively sinister overtones.

The Defendants' attorney has as much as admitted that the Defendants used the combination of the delay and denial of WBI's requested hearing and the criminal charges against Torbeck as a "hammer" to get Torbeck to surrender WBI's license for the Fayetteville facility. At the hearing on the Defendants' motion to dismiss this lawsuit, the attorney stated that:

> The government here only wanted to conduct proceedings that absolutely appeared to be necessary, and since it did not appear necessary and ultimately was not necessary, the license was voluntarily revoked and, at least according to the complaint, no hearing was conducted (Record of the District Court #27, Transcript of hearing of June 3, 1996, P. 9, Joint Appendix, P. 37).

NBI's Nashville plasma center was still in operation when the Defendants closed down WBI's Fayetteville center.

However, in September, 1992, without even waiting for Mr. Torbeck's response to certain "observations" made by FDA inspectors on the operation of the Nashville center, the Defendants Dykstra and Chesemore shut down that center, suspended NBI's license

(#1082-001) and announced the FDA's intent to permanently revoke that license (Amended Complaint, ¶¶31-35; pp. 22a-24a)

Torbeck could not afford to fight the FDA with both the Fayetteville and Nashville centers closed and no prospect of ever getting any sort of relief from the FDA, so he "voluntarily" surrendered NBI's license #1082-001, " . . . because of the lengthy time frame and costs needed to request a public hearing on the matter," if his experience with the FDA's handling of the closure of the Fayetteville center was any indication. The license revocation became effective on November 5, 1992 (Amended Complaint, ¶¶38-39; pp. 24a-25a).

Meanwhile, Torbeck did protest the manner in which Defendants Dykstra and Chesemore had shut down the Nashville center. He had responded in detail and within four days to each and every one of the "observations" made by FDA inspectors on September 14, 1992, upon which basis the Defendants had apparently based their decision to shut down the Nashville center (Amended Complaint, ¶¶33-34; p. 23a) Defendants Dykstra and Chesemore, however, had obviously decided to close the Nashville center before they even received Torbeck's responses to the "observations" (Amended Complaint, ¶35; pp. 23a-24c) Torbeck complained early and often that Defendants Dykstra and Chesemore violated Plaintiffs' due process rights by not following FDA custom and giving him an opportunity to respond to the "observations" before taking action upon them (Amended Complaint, ¶¶38-40; pp. 24a-25a).

Torbeck, WBI, and NBI filed their lawsuit in the United States District Court for Maryland, Greenbelt Division, on June 13, 1995. In it they alleged that the Defendants had shut down both the Fayetteville and Nashville plasma centers in violation of the Plaintiffs' right to due process of law under the Fifth Amendment to the Constitution of the United States (Amended Verified Complaint, ¶43; p. 25a.) They pleaded jurisdiction under 28 United States Code §1331 (Amd. Complaint ¶9; p. 18a). The gist of the Plaintiffs' claims was that their business activities had been destroyed without any sort of meaningful pre-deprivation or post-deprivation hearing or remedy. (*Id.*). Such claims are actionable against federal officials under *Bivens v. Six Unknown FBI Agents*, 403 U.S. 388 (1971). The Plaintiffs sought over $11,000,000 in special damages and lesser amounts in general compensatory and punitive damages.

On August 14, 1994, the Defendants moved to dismiss this lawsuit pursuant to FRCP 12 (Record of the District Court, #4), to which the Plaintiffs responded, after Court-approved extensions of time, on November 6, 1995 (Record of the District Court, #10).

On December 13, 1995, the Plaintiffs filed an Amended Verified Complaint that is appended hereto. The Defendants responded to this development with another motion to dismiss the lawsuit pursuant to FRCP 12 (Record of the District Court, #17) to which the Plaintiffs responded on March 15, 1996 (Record of the District Court, #18).

The Defendants' arguments in support of their motion were: a) that the Plaintiffs had failed to properly

plead their claim, i.e., that they had failed to meet a purported "heightened pleading" requirement in a case such as this; b) that the Plaintiffs failed to state a violation of the Fifth Amendment's due process clause; c) that the Defendants were entitled to qualified immunity even if the Plaintiffs' due process rights had been violated; d) that there were no "special factors" permitting this type of lawsuit; and e) that the Plaintiff Victor Torbeck lacked standing to be a plaintiff in the lawsuit (Record of the District Court, #17, pp. 1-2).

The Plaintiffs responded fully to this motion (Record of the District Court, #18).

On June 4, 1996, after a hearing and oral arguments, the previous day, Hon. Alexander Williams granted the Defendants' motion to dismiss pursuant to FRCP 12(b)(6) [Memorandum Opinion of June 4, 1996; Joint Appendix, pp. 54-57]. Judge Williams' opinion is appended hereto at pp. 10a-12a. The Court held that the Plaintiffs had failed to meet the purported heightened pleading requirements for suits such as this set forth in *Dunbar Corp. v. Lindsey*, 905 F.2d 754, 764 (4th Cir. 1990), and that the Defendants enjoyed qualified immunity because the Plaintiffs were unable, " . . . to articulate or point to a mandated time period by which a hearing on the revocation (of their licenses to operate plasma centers) was to occur, . . . " (Appendix, pp. 11a-12a). Indeed, the Court indicated that it was highly possible that none of the Plaintiffs' rights were violated at all, " . . . let alone 'clearly established' rights." (*Id.*, p. 12a). The Court also held that the Plaintiff Torbeck had no standing to participate in a lawsuit such as this because he did not allege, " . . . any injury separate and apart from that of an ordinary shareholder," (*Id.* p.

12a). Finally, the Court indicated verbally, albeit not in its written opinion, that none of the Defendants other than Dr. Kathryn Zoon and Thomas Bozzo could be liable to the Plaintiffs because:

> . . . they essentially signed letters. And that's just not enough. There is no vicarious liability. There is no respondeat superior under these type claims (Transcript of the Hearing, 6-3-96; Joint Appendix, pp. 51-52).

No testimony appeared on the record of this case, except to the extent that a verified Complaint may be said to be testimony. The Plaintiffs were never permitted to conduct any discovery; the Defendants never so much as filed an Answer to the Plaintiffs' Complaints. As the Court of Appeals noted in a footnote, Victor Torbeck's plea agreement is not mentioned in the Complaints in this case; it and many other "facts" upon which the Courts relied in this case are nothing more than assertions of the Defendants' attorney.

Plaintiffs appealed the dismissal of their lawsuit to the United States Court of Appeals for the Fourth Circuit. On August 19, 1997, that court affirmed the judgment of the District Court.

Unlike the District Court, which was unwilling even to admit any Constitutional problems with federal officials' not providing a hearing or any activity related to the setting of a hearing, for almost two years, the appellate Court at least conceded that it, " . . . generally would have concerns about the Constitutionality of a two-year delay in granting a post-suspension hearing for a license

to operate a business," (Opinion of the Court of Appeals, P. 2; This Brief, Appendix, P. 5a).

Despite this oblique recognition of a Constitutional violation in this case, the intermediate Court held that the District Court properly dismissed the Plaintiffs' lawsuit. It opined that the Defendants' plea of qualified immunity was well taken because:

> 1. Torbeck "voluntarily revoked" WBI's license to operate the Fayetteville facility, meaning, according to the Court, that Torbeck would be unable to argue that the revocation was unjustified (*Id.*, Appendix, P. 7a, note 2); ergo, the Defendants' suspension of the license was justified.
>
> 2. WBI could not have been seriously harmed due to the delay in providing it with a hearing because its license was ultimately "voluntarily" revoked (*Id.*, Appendix, P. 7a).
>
> 3. The Defendants, as government agents, had an interest in behaving just the way they did, because their "pursuit" of a plea bargain with Torbeck on the criminal charges against him was a reasonable effort at compromise and "conserved" government resources (*Id.*, Appendix, pp. 7a-8a); and

Incredibly, the Fourth Circuit purported to justify these multiple logical circles under the principles laid down in the case of *Federal Deposit Insurance Corporation v. Mallen*, 486 U.S. 230, 242, 108 S.Ct. 1780, 1877, 100 L.Ed.2d 265 (1988).

Not surprisingly, the Fourth Circuit's particular and peculiar efforts to apply the principles of *Mallen* to this

case was a new twist. The Defendants had argued that they were entitled to qualified immunity primarily because of a purported sparcity of authority indicating that the delay in deciding the Plaintiffs' administrative appeal of the revocation of WBI's license was Constitutionally infirm.

For this reason, the Plaintiffs filed a Petition for Rehearing with a suggestion for *en banc* consideration by the appellate Court, in which they argued as follows:

> 1. The Court's opinion ignored that part of the *Mallen* analysis that upholds, " . . . the importance of the private interest," of an individual alleging an Unconstitutional delay in receiving a hearing after his property has been taken. By various elliptical means, all of which boiled down to the notion that "the end justified the means," the Court essentially ignored the fact that the Defendants destroyed a viable business and its owners' livelihood.
>
> 2. The Court's reasoning was essentially that the Defendants' actions were completely justified by the fact that Torbeck ultimately surrendered WBI's Fayetteville license. This runs counter to the entire tenor of the *Mallen* case, which this Court declined to declare moot despite the plaintiff's criminal conviction (affirmed on appeal) of the very charges that had formed the basis for the administrative "taking" of his property.
>
> 3. The Court's attempt to apply the *Mallen* analysis ignored the fact that in this case, unlike *Mallen,* there was no linkage between the criminal charges against the plaintiff Victor Torbeck and the administrative charges that led to the

suspension of WBI's license. Unlike the plaintiff in *Mallen*, neither Torbeck nor WBI could use the criminal charges against Torbeck as, " . . . an additional forum at which to demonstrate that the suspension [of the license] was unjustified," *Mallen*, 486 U.S. at 248, 108 S.Ct. at 1191, because there simply was no connection between the criminal charges and the suspension.

4. The Court in essence approved the Defendants' use of delay in processing WBI's administrative appeal as a tactic to "hammer" Torbeck into giving up WBI's Fayetteville license. On its face, this is a disgraceful and outrageous abuse of judicial authority, and a perfidiously perverse application of *Mallen*, so as to render meaningless the right to due process of law.

ARGUMENT

In *Bivens v. Six Unknown Agents of the Federal Bureau of Investigation*, 403 U.S. 388, 91 S.Ct. 1999, 29 L.Ed.2d (1971), this Court held that our citizens may sue individual federal officials for violating the citizens' rights under the Constitution of the United States. Such damage suits are cognizable for alleged violations of the right to due process of law under the Fifth Amendment to the Constitution, *Sequin v. Eider*, 645 F.2d 804 (9th Cir., 1981), see *Davis v. Passmore*, 442 U.S. 228, 99 S.Ct. 2264, 60 L.Ed.2d 816 (1979).

The essence of due process of law, of course, is the right to be heard, *Matthews v. Eldridge*, 424 U.S. 319 (1976).

In this case, the Defendants were obligated to provide a hearing to the Plaintiffs not only under the Constitution, but under the very regulations of their own government employer, the FDA. 21 Code of Federal Regulations, Chapter 1, Part 12, subpart B specifically required the Defendant David Kessler to insure that this precious right of the plaintiffs was provided to them.

The Defendants' failure to follow these regulations indicates a per se Constitutional violation, *Bills v. Henderson*, 631 F.2d 1287 (6th Cir., 1980), *Mantilla v. Immigration & Naturalization Service*, 926 F.2d 162 (2d Cir., 1991).

This Court has always been:

> . . . concerned about the importance of providing prompt post-deprivation procedures in situations in which an agency's discretionary impairment of an individual's property is not preceeded by an opportunity for a pre-deprivation hearing,

Federal Deposit Insurance Corporation v. Mallen, 486 U.S. 230, 240-241, 108 S.Ct. 1780, 1788, 100 L.Ed.2d 265 (1988).

As the Court stated in *Mallen, Id.*, there is a point at which an unjustified delay in *completing* a post-deprivation proceeding would become a Constitutional violation," citing *Cleveland Board of Education v. Loudermill*, 470 U.S. 532, 547, 105 S.Ct. 1487, 1496, 84 L.Ed.2d 494 (1985). [emphasis added].

This point may be determined by analyzing the following three factors:

> . . . the importance of the private interest and the harm to this interest occasioned by the

> delay; the justification offered by the government for delay and its relations to the underlying governmental interest; and the likelihood that the interim decision may have been mistaken.

Mallen, 486 U.S. at 242, 108 S.Ct.

In this case, as we have seen, the appellate Court essentially took Torbeck's eventual surrender of WBI's license as its license to ignore any serious consideration of the first and third factors. As to the second *Mallen* factor, the Court purported to find an important government interest in "conserving resources" as a justification for the Defendants' never having given the Plaintiff a hearing.

On its face, of course, this is a gross misapplication of the standards set forth in *Mallen*. It is, however, far more significant than that: it is essentially a complete denigration of the entire concept of due process of law. What the Fourth Circuit has done in this case is to say that since the government managed ultimately to get WBI's license, the Plaintiff's due process rights simply do not matter; the ultimate result justifies the Defendants' refusal to give WBI and Torbeck their otherwise required hearing.

There is a sharp irony in the Fourth Circuit's efforts to apply *Mallen* principles to this case. It is that, if anything, the Plaintiffs in this case had a better argument for Unconstitutional delay than did the plaintiff in *Mallen*. That plaintiff, after all, had only to wait 90 days for a *decision* regarding his license; the Plaintiffs in this case waited two years and were never even told when, if ever,

they would get a *hearing* concerning their license. Furthermore, the plaintiff in *Mallen* had an opportunity to resolve the allegations that led to the suspension of his license in a criminal forum as well as before the government agency that challenged it. In this case, the Plaintiffs had no such opportunity, as the criminal charges against them were unrelated to the charges that led to the suspension of their license. Finally, of course, the enormity of the delay in this case was patent; in *Mallen*, even without the application of the three factors set out above, it was a much "closer" call.

The Defendants' treatment of the Plaintiffs and their disgraceful efforts to justify it so offend any reasonable notion of "fair play" as to be Unconstitutional on its face, *Galvan v. Press*, 347 U.S. 522 (1954). The notion that the qualified immunity defense would protect the Defendants is equally offensive. The reaction of the Courts below to this case clearly defies any notion of reasonable Constitutional jurisprudence and therefore represents such a distant departure, " . . . from the accepted and usual course of judicial proceedings . . . as to call for an exercise of this Court's supervising power," Supreme Court Rule 10(a), by granting this Petition.

Furthermore, in this case, unlike *Mallen*, the question before the Court is not the propriety of formal government procedures setting time limits for a post-deprivation hearing, but the propriety of individual government officials' personal manipulation of government hearing procedures so as (to put matters in the best light possible for them) to make their jobs easier and/or to achieve a certain goal without having to bother with providing one of their "clients" with any due process of law. Put in more

formal terms, this case presents the important federal question, never decided by this Court, of how to apply the standards set forth in *Mallen* to allegations of due process violations by individual government officers, thereby justifying the granting of this Petition under Rule of the Supreme Court 10(c).

Additionally, there is a Constitutional question of considerable importance in this case that was not apparent in *Mallen*. It is this: to what extent may government officials justify delay in providing a post-deprivation hearing to an individual whose property they have taken based upon their belief that they will ultimately be able to permanently secure the property in unrelated or collateral proceedings? Rule 10(c) of this Court points to the granting of this Petition so that this question may be answered.

Finally, "application" of *Mallen* principles by the Courts below and their use of FRCP 12(b)(6) to dismiss this lawsuit, are so egregiously erroneous as to create a real conflict with the *Mallen* opinion itself, thereby justifying the granting of this Petition under Supreme Court Rule 10(c).

Respectfully submitted,

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Victor H. TORBECK; WBI Enterprises, Incorproated, [sic] formerly known as Worldwide Biologicals, Incorporated; nashville [sic] Biologicals, Incorporated, Plaintiffs-Appellants,

v.

Kathryn ZOON, Ph.D.; Thomas S. Bozzo; Gary Dykstra; Ronald Chesemore; Gerald V. Quinnan; David Kessler, Defendnts [sic]-Appellees.

No. 96-1962.

United States Court of Appeals, Fourth Circuit.

Argued May 7, 1997.

Decided Aug. 29, 1997.

Appeal from the United States District Court for the District of Maryland, at Baltimore. Alexander Williams, Jr., District Judge.

ARGUED: Philip Clyde Kimball, Louisville, Kentucky, for Appellants. Paige Elizabeth Harrison, Associate Chief Counsel for Enforcement, FOOD AND DRUG ADMINISTRATION, Rockville, Maryland, for Appellees.

ON BRIEF: Lynne A. Battaglia, United States Attorney, Allen F. Loucks, Assistant United States Attorney, Baltimore, Maryland, for Appellees.

Before WILKINSON, Chief Judge, MICHAEL, Circuit Judge, and COPENHAVER, United States District Judge

for the Southern District of West Virginia, sitting by designation.

OPINION

PER CURIAM:

Plaintiffs-Appellants Victor Torbeck, Nashville Biologicals, Inc. (NBI), and Worldwide Biologicals, Inc. (WBI) brought an action against six current and former employees of the United States Food and Drug Administration (FDA), seeking compensatory and punitive damages for an alleged deprivation of their rights under the Fifth Amendment's Due Process Clause. The district court determined that the plaintiffs' complaint did not allege a violation of clearly established rights and dismissed the action on the grounds of qualified immunity. We affirm.

I.

NBI and WBI are corporations which engaged in the business of collecting, storing, selling, and distributing human plasma and other blood products. Torbeck was the Chief Executive Officer of these companies as well as one of two shareholders. Defendants are all officers of the FDA, the agency in charge of regulating and licensing plasma distributors. The complaint alleges that on May 5, 1992, one of the defendants notified WBI that the WBI plasmapheresis center in Fayetteville, North Carolina, had failed to pass an inspection and would not be allowed to continue operating. Torbeck sent a letter on May 21 requesting an abeyance of the suspension, but

this request was denied in a letter from defendant Kathryn Zoon, a director at the FDA. According to the complaint, Zoon said that WBI would have its license permanently revoked but would have an opportunity to contest this decision at a hearing. Plaintiffs claim to have requested both a hearing and information regarding the revocation. However, the FDA did not provide any of the information requested and did not schedule a hearing. On March 22, 1993, the FDA announced an opportunity for a hearing in the Federal Register but did not specify a date. See 58 Fed.Reg. 15351-53 (1993).

On April 29, 1994, Torbeck entered into a plea agreement for three counts of violating the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., and one count of making a false statement in violation of 18 U.S.C. § 1001. As part of the agreement, Torbeck agreed to the revocation of the WBI Fayetteville Center license.[1]

Concurrently with its investigation of WBI's Fayetteville Center, the FDA was also investigating NBI's plasmapheresis center located in Nashville, Tennessee. On September 30, 1992, the FDA suspended the Nashville Center's license to operate. Torbeck requested an abeyance of the suspension, which was denied. On October 5,

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[1] The complaint did not discuss the plea agreement; it said nothing about whether or how the WBI Fayetteville Center's license was ultimately revoked. At oral argument before the district court, however, plaintiffs acknowledged the plea agreement, and in their brief to this court they discuss the agreement in their Statement of Facts. See Brief for Appellants at 8.

1992, Torbeck requested in a letter to the FDA that the license be revoked without a hearing.

Plaintiffs brought this action, pursuant to Bivens v. Six Unknown Named Agents of the Fed. Bureau of Narcotics, 403 U.S. 388 (1971), alleging that defendants had violated plaintiffs' constitutional rights under the Fifth Amendment's Due Process Clause by failing to provide a hearing either before or promptly after the suspension of the licenses. Defendants moved to dismiss under Fed.R.Civ.P. 12(b)(6), asserting that they had qualified immunity from the suit. The district court agreed and dismissed the action.

II.

Plaintiffs claim that defendants violated their rights under the Due Process Clause by failing to provide the following: (a) a hearing prior to the suspension of the licenses, (b) a hearing promptly after the suspension of the WBI Fayetteville Center license, and (c) a hearing promptly after the suspension of the NBI Nashville Center license. We examine these claims in turn.

A.

In their complaint plaintiffs assert that defendants violated the Due Process Clause by "not provid[ing] Plaintiffs with any meaningful opportunity to be heard before shutting down the Fayetteville Center and the Nashville Center." J.A. 24. However, plaintiffs conceded before the district court that they had no right to a pre-suspension hearing. J.A. 47. Plaintiffs cannot revive that

argument here. In any event, there are public health justifications for allowing FDA suspensions to take effect immediately. See, e.g., Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594, 598-600 (1950) (upholding seizures of misbranded articles under the Food, Drug & Cosmetics Act); North Am. Cold Storage Co. v. City of Chicago, 211 U.S. 306, 315-21 (1908) (upholding government authority to seize and destroy potentially infected food).

B.

Plaintiffs claim that defendants violated their right to due process by not providing a hearing within two years after the suspension of the WBI Fayetteville Center license. The license was suspended on May 5, 1992, and the FDA did not provide a hearing on that suspension within the next two years. On April 29, 1994, Torbeck voluntarily agreed to rescind the license as part of a plea agreement.

Although we generally would have concerns about the constitutionality of a two-year delay in granting a post-suspension hearing for a license to operate a business, we do not find that the district court erred in granting the defendants qualified immunity. Defendants are only liable for the violation of "clearly established statutory or constitutional rights of which a reasonable person would have known." Harlow v. Fitzgerald, 457 U.S. 800, 818 (1982). The due process right to a prompt hearing carries no hard deadlines. See, e.g., Ritter v. Cohen, 797 F.2d 119, 124 (3d Cir.1986) ("[N]o fixed rule governs the time in which a post-termination appeal must be decided."); Kelly v. Railroad Retirement Bd., 625 F.2d

486, 490 (3d Cir.1980) ("[T]here is no magic length of time after which due process requirements are violated."). The Supreme Court uses a three-factor balancing test for determining how long an agency can delay in affording a post-suspension hearing and decision. See, e.g., Federal Deposit Ins. Corp. v. Mallen, 486 U.S. 230, 242 (1988). We have recognized that when the inquiry into the protections afforded by a constitutional right "requires a 'particularized balancing' that is subtle, difficult to apply, and not yet well defined," those protections will "only infrequently . . . be 'clearly established.' " DiMeglio v. Haines, 45 F.3d 790, 806 (4th Cir.1995) (discussing constitutional protections afforded to public employee speech).

Moreover, this case is unique in that plaintiffs did not continue to contest the validity of the FDA's suspension after the two-year delay. Instead, Torbeck voluntarily rescinded the license as part of a plea bargain on criminal charges. Plaintiffs cannot now contend that the license was improperly revoked when the license was voluntarily rescinded as part of a bargain with the government. Cf. Vennes v. An Unknown Number of Unidentified Agents, 26 F.3d 1448, 1452 (8th Cir.1994) ("By pleading guilty, [plaintiff] elected to forego the postdeprivation process best suited to determining whether the agents in fact violated his due process rights – the criminal trial."). In order to contest the validity of the suspension, plaintiffs needed to continue their administrative appeal until the agency reached a decision. Plaintiffs' failure to exhaust the avenues of administrative relief has waived their claim that the license was improperly revoked. Cf. Rana v. United States, 812 F.2d 887, 890 (4th Cir.1987) ("When an argument concerns procedural rights within

the purview of agency expertise, and a plaintiff fails to raise the argument before the agency, courts will entertain the argument on appeal only if it is 'jurisdictional' or if there are compelling reasons for its novelty."). Plaintiffs conceded this point at oral argument.[2] With these circumstances in mind we examine the underlying merits of plaintiffs' claim. The three factors used by the Court in Mallen for determining the constitutionality of a delay in a post-suspension hearing are: "the importance of the private interest and the harm to this interest occasioned by the delay; the justification offered by the government for delay and its relations to the underlying governmental interest; and the likelihood that the interim decision may have been mistaken." Mallen, 486 U.S. at 242. As to the first Mallen factor, a business whose license is suspended is not seriously harmed by a delayed hearing if the validity of the suspension is not contested. We agree with the district court that, since the license was "voluntarily surrender[ed]," the delay in reaching a final determination was "harmless, at best." J.A. 51. As to the second factor, the government had an interest in pursuing

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[2] We are not saying that plaintiffs needed to exhaust their administrative remedies before bringing the current action, since the basis of plaintiffs' claim is that there was "an unreasonable or indefinite timeframe for administrative action." McCarthy v. Madigan, 503 U.S. 140, 147 (1992). However, plaintiffs should not have voluntarily rescinded the license if they wished to challenge the validity of the suspension along with the constitutionality of the delay. As their action now stands, plaintiffs can challenge the delay in providing a hearing, but they cannot contend that the original suspension or eventual revocation was unjustified.

the possibility of a plea bargain before it granted a hearing. A plea bargain is an opportunity to reach a mutually acceptable compromise, and it also conserves government resources. Finally, as to the third factor, we must consider the government's decision to suspend the license to be correct, since Torbeck's agreement to surrender the license waived the plaintiffs' claim to the contrary.

Thus, in looking at all the factors, we cannot conclude that the defendants violated any clearly established constitutional rights. Although we have concerns about the length of the delay in this case, we believe that the special circumstances surrounding the surrender of the license offer significant justification for that delay. Cf. Mallen, 486 U.S. at 242 ("For even though there is a point at which an unjustified delay in completing a post-deprivation hearing 'would become a constitutional violation,' the significance of such a delay cannot be evaluated in a vacuum." (citations omitted)). Under all the circumstances here, we conclude that the defendants are entitled to qualified immunity.

C.

Plaintiffs also contend that the defendants violated their right to a post-suspension hearing for the NBI Nashville Center license. The FDA suspended the license on September 30, 1992. On October 5, 1992, a mere five days later, Torbeck wrote a letter to the FDA agreeing to the revocation of the license. Plaintiffs certainly had no "clearly established" due process right to a hearing within five days of the suspension of the license. Plaintiffs claim that they were given "no other choice" but to

surrender their license "[b]ecause [the FDA] had informed Victor Torbeck that NBI had no right to request an abeyance of the revocation of the subject licenses, and because Defendants had denied WBI a hearing regarding the suspension and revocation of the licenses pertaining to the Fayetteville Center." J.A. 22, 23. Even if plaintiffs feared that the hearing would be delayed, however, they were under no compulsion to voluntarily agree to the revocation of the license. The actions of defendants (essentially, accepting the surrender of the license after five days) did not violate any clearly established rights of the plaintiffs.

III.

We hold that the district court properly granted qualified immunity to the defendants against the plaintiffs' due process claims. We therefore affirm the district court's dismissal of the plaintiffs' complaint without leave to amend.

AFFIRMED

Affirmed by unpublished per curiam opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

VICTOR H. TORBECK, *et al.*	:	
Plaintiffs,	:	Civil Action No. AW 95-1761
v.	:	
KATHRYN ZOON, Ph.D., *et al.*	:	
Defendants.	:	

MEMORANDUM OPINION

Plaintiffs, Victor H. Torbeck ("Torbeck"), Worldwide Biologicals, Inc. ("WBI"), and Nashville Biologicals, Inc. ("NBI") sued six current and former employees of the United States Food and Drug Administration ("FDA"), in their individual capacities, seeking compensatory and punitive damages for an alleged deprivation of their Fifth Amendment right to due process of law. Plaintiffs alleged that these FDA employees deprived them of their right to a meaningful hearing before their licenses to manufacture biological products were revoked.

Pending before the Court is the Defendants' Motion to Dismiss Plaintiffs' Amended Verified Complaint. The Court conducted a hearing in open court on the record on June 3, 1996. For the reasons stated in open court and set forth more clearly below, the Court will grant the Defendants' Motion to Dismiss.

When ruling on a Rule 12(b)(6) motion, the Court must accept the complaint's allegations as true and liberally construe the complaint as a whole. *Jenkins v. McKeithen*, 395 U.S. 411, 321 (1969); *Finlator v. Powers*, 902 F.2d 1158 (4th Cir. 1990). A court should not dismiss a complaint unless it appears beyond doubt that the plaintiff can prove no set of facts entitling him to relief. *Conely v. Gibson*, 355 U.S. 41, 45-46 (1957); *Faulkner Advertising Assoc. v. Nissan Motor Corp.*, 905 F.2d 769, 771-71 (4th Cir. 1990).

Measured against this standard, the Court finds that the Plaintiffs have to stated a claim upon which relief can be granted. First, the Plaintiffs have not satisfied the heightened pleading requirement set forth in this Circuit. *Dunbar Corp. v. Lindsey*, 905 F.2d 754, 764 (4th Cir. 1990) (requiring the plaintiff to specify the clearly established rights alleged to have been violated in actions against government officials for money damages).

Second, the Defendants, as government officials, enjoy qualified immunity under the circumstances of this case. *Slattery v. Rizzo*, 939 F.2d 213, 216 (4th Cir. 1991) (holding that government officials performing discretionary functions are shielded from civil liability to the extent their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have known).

According to the allegations set forth in the amended complaint, both licenses in question were voluntarily surrendered by Plaintiffs. Moreover, the amended complaint does not state nor were Plaintiffs able, during the hearing, to articulate or point to a mandated time period by

which a hearing on the revocation was to occur. In fact, reviewing the amended complaint in its entirety and all reasonable inferences therefrom, the Court is compelled to conclude that Defendants did not violate "clearly established" statutory or constitutional rights. Furthermore, the Court has grave reservations whether Plaintiffs were denied any rights under these circumstances, let alone "clearly established" rights.

Third, Plaintiff Torbeck has not alleged any injury separate and apart from that of an ordinary shareholder that would give him standing to maintain any cause of action against these Defendants. *Smith Setzer & Sons, Inc. v. South Carolina Procurement Review Panel,* 20 F.3d 1311, 1317-18 (4th Cir. 1994).

Accordingly, the Court will grant the Motion to Dismiss the Amended Verified Complaint as to each of the six Defendants. The Court does not believe that a second amended complaint will correct the deficiencies. A separate Order consistent with this opinion will issue.

June 4, 1996
Date

/s/ Alexander Williams, Jr.
Alexander Williams, Jr.
United States
District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

VICTOR H. TORBECK, *et al.*	:	
Plaintiffs,	:	Civil Action No. AW 95-1761
v.	:	
KATHRYN ZOON, Ph.D., *et al.*	:	
Defendants.	:	

ORDER

For the foregoing reasons, and for the reasons stated in open court on the record, IT IS this 4th day of June, 1996, hereby ORDERED:

1. That Defendants' Motion to Dismiss Plaintiffs' Amended Verified Complaint, BE and the same hereby IS, GRANTED.

2. That the Clerk of the Court CLOSE this case.

3. That the Clerk of the Court mail a copy of this Order to all parties of record.

/s/ Alexander Williams, Jr.
Alexander Williams, Jr.
United States
District Judge

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

FILED
October 27, 1997

No. 96-1962
CA-95-1761-AW

VICTOR H. TORBECK; WBI ENTERPRISES, INCORPORATED, formerly known as Worldwide Biologicals, Incorporated; NASHVILLE BIOLOGICALS, INCORPORATED

Plaintiffs - Appellants

v.

KATHRYN ZOON, Ph.D.; THOMAS S. BOZZO; GARY DYKSTRA; RONALD CHESEMORE; GERALD V. QUINNAN; DAVID KESSLER

Defendants - Appellees

On Petition for Rehearing with Suggestion for Rehearing In Banc

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The appellants' petition for rehearing and suggestion for rehearing in banc were submitted to this Court. As no member of this Court or the panel requested a poll on the suggestion for rehearing in banc, and

As the panel considered the petition for rehearing and is of the opinion that it should be denied.

IT IS ORDERED that the petition for rehearing and suggestion for rehearing in banc are denied.

For the Court,

/s/ Patricia S. Connor
Patricia S. Connor
CLERK

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

Victor H. Torbeck, et al., Plaintiffs, v. Kathryn Zoon, Ph.D., et al., Defendants.	Civ.No. AW-95-1761

AMENDED VERIFIED COMPLAINT
(With Jury Demand)

Plaintiffs, Victor Torbeck, WBI Enterprises, Inc. ("WBI") and Nashville Biologicals, Inc. ("NBI"), by counsel, pursuant to FRCP 15a, and for their Amended Complaint against the Defendants, Kathryn Zoon, Ph.D, Thomas S. Bozzo, Gary Dykstra, Ronald Chesemore, Gerald V. Quinnan, Jr., and David Kessler, state and represent as follows:

I. Parties to Lawsuit

1. Plaintiff, Victor Torbeck, is now, and at all times material to this lawsuit has been, a resident of Cincinnati, Hamilton County, Ohio and chief executive officer of the Plaintiff WBI. Victor Torbeck and his wife, Carol L. Torbeck, have at all relevant times been the sole shareholders of WBI.

2. Plaintiff, WBI, formerly known as Worldwide Biologicals, Inc., is an Ohio Corporation with its principal place of business located at 1085 Ohio Pike, Cincinnati,

Ohio, Formerly engaged in the business of plasma and blood products collection, storage, sale and distribution.

3. Plaintiff, NBI, is an Ohio Corporation with its principal place of business located at 1085 Ohio Pike, Cincinnati, Ohio, formerly engaged in the business of plasma and blood products collection, storage, sale and distribution. At all relevant times, WBI was the sole shareholder of NBI.

4. The Defendant, David Kessler, was at all times material to this lawsuit the Commissioner of the United States Food and Drug Administration ("FDA") and is a resident of Silver Spring, Maryland.

5. The Defendants, Gerald V. Quinnan, Jr. and Kathryn Zoon, Ph.D., were at various times material to this lawsuit the Director of the Center for Biologics and Evaluation Research of the United States FDA. Mr. Quinnan is a resident of Rockville, Maryland and Dr. Zoon is a resident of Kensington, Maryland.

6. The Defendant, Ronald G. Chesemore, was at all times material to this lawsuit the Associate Commissioner for Regulatory Affairs of the United States FDA and is a resident of Germantown, Maryland.

7. The Defendant, Gary Dykstra, was at all times material to this lawsuit an assistant to the Defendant Chesemore in the United States FDA and is a resident of Silver Spring, Maryland.

8. The Defendant, Thomas S. Bozzo, was at all times material to this lawsuit the Director of the Office of Compliance of the United States FDA and is a resident of Silver Spring, Maryland.

II. Venue and Jurisdiction

9. This Court has jurisdiction over the claims of the Plaintiffs and the persons of the Defendants under and by virtue of the Fifth Amendment of the Constitution of the United States and 28 United States Code Section 1331.

10. Venue is proper in this Court under and by virtue of 28 United States Code Section 1391(e), as Defendants, or some of them, reside in this federal judicial district.

III. Wrongdoing of Defendants

A. The Fayetteville Plasmapheresis Center

11. From approximately April 1990 to May 1992, WBI successfully and profitably owned and operated a plasmapheresis center located at 508 A Owen Drive, Fayetteville, North Carolina (The "Fayetteville Center"). The Fayetteville Center was operated pursuant to U.S. License Number 0832-003 issued by the FDA.

12. WBI and Victor Torbeck invested considerable capital and devoted considerable time and effort to the successful operation and growth of the Fayetteville Center.

13. By telephone and then by letter to Victor Torbeck dated May 5, 1992, Defendant Thomas S. Bozzo relayed that the approval for the Fayetteville Center to collect and store Source Plasma was rescinded.

14. By letter dated May 21, 1992, to Defendant Bozzo from Victor Torbeck, WBI requested an abeyance of the recision relayed by Defendant Bozzo. In support of

this request, WBI provided Defendant Bozzo with a written plan to address various concerns of the FDA.

15. By letter to Victor Torbeck dated June 15, 1992, Defendant, Kathryn Zoon, Ph.D. relayed:

(a) the denial of WBI's request that the revocation of the license be held in abeyance;

(b) the intention to revoke U.S. License Number 0832-003 pertaining to the Fayetteville Center;

(c) the *intention* to issue a notice of opportunity for hearing pursuant to 21 C.F.R. 12.21 (b);

(d) that WBI had the option of waiving the opportunity for a hearing by contacting Defendant Bozzo within ten (10) days and provided his address and telephone number; and

(e) that if WBI did not respond within the prescribed time, they would proceed pursuant to the regulations governing *formal evidentiary public hearings*.

Dr. Zoon directed disposition of the inventory.

16. WBI greatly desired to receive a "formal, evidentiary, public hearing" and, accordingly, did *not* contact Defendant Bozzo to waive its opportunity for a hearing.

17. The FDA acknowledged WBI's request for a hearing by letter dated June 29, 1992, from Nancy A. Murphy, Chief, Recalls and Administrative Actions Branch, Office of Compliance, Center for Biologics Evaluation and Research.

18. The actions of the Defendants described above, required WBI to cease its normal business activities at the Fayetteville Center as of May 15, 1992, resulting in substantial loss of business and other damages and such actions had the predictable result of putting that center out of business. In addition, the actions described above required Plaintiff WBI to eventually destroy large quantities of inventories at substantial economic loss.

19. Eventually, in September 1992, the FDA confiscated all of the product inventory which had been produced at the Fayetteville Center.

20. On May 9, 1992, WBI made a written request to the FDA pursuant to the Freedom Of Information Act requesting information and documents regarding the FDA inspections of the Fayetteville Center. In a letter dated May 28, 1992, Mr. Wade E. White acknowledged the FDA's receipt of WBI's request and led WBI to believe that a response would be made as soon as possible.

21. By telephone on June 22, 1992; November 25, 1992; and March 17, 1993, WBI repeated its request for information from the FDA pursuant to the Freedom of Information Act. No information was provided.

22. By letter from Victor Torbeck to Mr. Wade E. White dated March 19, 1993, WBI again requested information and documents regarding the FDA inspections of the Fayetteville Center. Mr. Torbeck also relayed his belief that the requested items and other information were being intentionally withheld from WBI. Finally, in his letter, Victor Torbeck put the FDA on notice that he believed that his:

> " . . . right to a public hearing concerning the suspension of the license at the same Fayetteville Center has been held up for a long period of time for no apparent reason. I was told in May, 1992 by Mr. Fenner that six (6) months was considered the normal length of time for a notice of a public hearing to be made. It has now been ten (10) months."

23. Throughout this entire period and beyond, the Fayetteville Center was not permitted to engage in business activities resulting in substantial loss and damages to WBI and the eventually permanent closing of that facility due to the financial distress caused by the actions set out herein.

24. Defendant Kathryn C. Zoon waited until March 19, 1993, to file a notice to be published in the *Federal Register* on March 22, 1993, announcing an "opportunity for a hearing on a *proposal* to revoke" U.S. License Number 00832-003 pertaining to the Fayetteville Center.

25. By letter from Victor Torbeck dated April 12, 1993, WBI again duly and properly requested a hearing on the proposal to revoke the above referenced license and requested information regarding the "hearing" so that he would "know what is expected of me and what to expect of the hearing personnel and procedures."

26. By letter from Victor Torbeck dated May 20, 1993, WBI again requested a public hearing regarding the proposal to revoke the above referenced license and transmitted documents, evidence and arguments in support of its position.

27. In spite of the repeated, timely and proper requests of WBI, the Defendants herein intentionally refused and failed to grant to WBI the hearing which it was constitutionally entitled to receive.

28. All actions of the Defendants set out herein were done in their individual capacities while acting under the color of their respective positions with the FDA and were done at the direction and/or encouragement of each of the other named Defendants and other individuals at the FDA.

B. The Nashville Center

29. Beginning in approximately April 1989, NBI successfully and profitably owned and operated a plasmapheresis center located at 3025 Nolensville Road, Nashville, Tennessee (the "Nashville Center").

30. NBI, WBI and Victor Torbeck invested considerable capital and devoted considerable time and effort to the successful operation and growth of the Nashville Center.

31. On or about July 6, 1989, U.S. Establishment License Number 1082-001 was issued by the FDA for the Nashville Center. In addition, a product license was issued pertaining to the collection and storage of Source Plasma by the Nashville Center.

32. From approximately August 24, 1992, through approximately September 14, 1992, representatives from the FDA inspected the Nashville Center.

33. At the conclusion of that inspection on September 14, 1992, NBI was presented with a list of observations made by the FDA representatives during the inspection (the "483").

34. With a lengthy letter from Victor Torbeck dated September 25, 1992, NBI promptly replied and responded to the "observations" noted in the 483 and transmitted numerous documents in support of its positions.

35. Before NBI's response to the 483 could have been received and meaningfully considered by the FDA, Defendants, Gary Dykstra and Ronald S. Chesemore, notified NBI by letter dated September 30, 1992:

(a) of the suspension of U.S. Establishment License Number 1082-001 pertaining to the Nashville Center;

(b) of the suspension of the product license for Source Plasma issued to Nashville;

(c) of the intention to permanently revoke the establishment and product licenses issued to the Nashville Center;

(d) of the intention to issue a notice of opportunity for hearing, pursuant to 21 C.F.R. 12.21 (b).

(e) that NBI had the option of waiving the opportunity for a hearing by contacting Defendant Bozzo within ten (10) days and provided his address and telephone number; and

(f) that if NBI did not respond within the prescribed time, they would proceed pursuant to the regulations governing *formal evidentiary public hearings.*

In addition, NBI was directed to destroy plasma units in its inventory.

36. On October 1, 1992, Victor Torbeck, acting in behalf of NBI, telephoned Defendant Bozzo and requested an abeyance of the revocation of license 1082. Defendant denied this request and informed Victor Torbeck that he would not accept a request for such abeyance.

37. The actions of the Defendants described herein, required NBI to cease its normal business activities at the Nashville Center as of September 30, 1992, resulting in substantial loss of business and other damages and such actions had the predictable result of putting that center out of business. In addition, the actions described above required Plaintiff NBI to eventually destroy large quantities of inventories at substantial economic loss.

38. Because Defendant Bozzo had informed Victor Torbeck that NBI had no right to request an abeyance of the revocation of the subject licenses, and because Defendants had denied WBI a hearing regarding the suspension and revocation of the licenses pertaining to the Fayetteville Center, Victor Torbeck wrote Defendant Bozzo on October 5, 1992, and "requested" the revocation of the license for the Nashville Center. In that letter, Victor Torbeck stated:

> "I am doing this because of the lengthy time frame and costs needed to request a public hearing on this matter. I do want it known, however, that I feel this suspension and revocation was done without CBER having all the facts in this matter. . . . Only the opinions and statements of

the inspector were taken into consideration in the making of the suspension decision."

39. By letter dated November 5, 1992, signed by Defendant Quinnan for Defendant Zoon, Victor Torbeck and NBI were notified that Establishment License No. 1082 and the Product License for Source Plasma were revoked, effective that date.

40. By letter from Victor Torbeck dated November 10, 1992, NBI responded to the November 5th letter by again emphasizing that License 1082 was revoked only because NBI was "given no other choice to request the revocation be held in abeyance pending resolution of the matters involved." In that letter, NBI clearly and expressly stated that it had been denied due process of law.

41. Because of the actions of Defendants set out herein, NBI was forced to close the Nashville Center, terminate all employees and dispose of the plasma on hand all of which directly resulted in substantial damage and loss.

42. All actions of the Defendants set out herein were done in their individual capacities while acting under the color of their respective positions with the FDA and were done at the direction and/or encouragement of each of the other named Defendants and other individuals at the FDA.

IV. Claims

43. The actions described above constituted a deprivation of the Plaintiffs' rights in their property without

due process of law in violation of the Fifth Amendment to the Constitution of the United States in that:

(a) The Defendants did not provide Plaintiffs with any meaningful opportunity to be heard before shutting down the Fayetteville Center and the Nashville Center and suspending and revoking the pertinent licenses, all as more particularly described herein;

(b) The Defendants did not provide the Plaintiffs with any meaningful remedies after shutting down the Fayetteville Center and Nashville Center and suspending and revoking the pertinent licenses, all as more particularly described herein, in that:

(i) the hearing/appeal procedure that was available required Plaintiffs to wait well over one year for a determination on the merits of their hearing/appeal;

(ii) the hearing/appeal procedure did not permit Plaintiffs to operate their lawful businesses pending final determination of their hearing/appeal;

(iii) the hearing/appeal procedure that was available contained no provision for compensating the Plaintiffs for losses incurred during its pendency;

(iv) Plaintiffs were never given a hearing/appeal; and

(v) Congress provided no procedures or remedies that could

be reasonably substituted for this action.

44. No special factors exist which prohibit the Court from entertaining this action.

V. Damages to the Plaintiffs

45. As a direct and proximate result of the wrongful acts of Defendants, Plaintiffs WBI and NBI have suffered and will continue to suffer lost profits and business income of more that $11,081,184.00.

46. As a direct and proximate result of the wrongful acts of Defendants, Plaintiff Victor Torbeck has suffered pecuniary losses derived from the losses suffered by WBI as described herein. Additionally, Plaintiff Victor Torbeck has suffered humiliation, embarrassment, mental anguish, grief, mental and emotional distress, and personal indignity as a direct and proximate result of the wrongful acts of Defendants, for which he is entitled to recover general compensatory damages in the approximate sum of $1,000,000.00.

47. Because of the willful, malicious and outrageous nature of the wrongful actions of Defendants, Plaintiffs are entitled to recover punitive damages from each of the Defendants in the respective sum of $250,000.00 per Defendant.

VI. Prayer for Relief

WHEREFORE, the Plaintiffs, Worldwide Biologicals, Inc., Nashville Biologicals, Inc. and Victor Torbeck each demand as follows:

A. Judgment against Defendants, jointly and severally, for special and compensatory damages in the amounts set forth above plus any other amounts to be determined by a jury of Defendant' peers;

B. Judgment against Defendants, individually, for punitive damages;

C. A trial by jury;

D. An Order of Court forbidding any retaliation against the Plaintiffs as a result of the filing of this lawsuit;

E. Recovery of their costs and attorney fees herein expended; and

F. Any and all other relief to which they may be entitled.

Date: December 11, 1995.

/s/ C Thomas Brown
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VERIFICATION

Plaintiff, Victor Torbeck, individually, as past President of WBI Enterprises, Inc. and as past President of Nashville Biologicals, Inc., states that he has read the foregoing Verified Complaint, and swears that the statements contained therein are true as he verily believes.

/s/Victor Torbeck
VICTOR TORBECK

State of Ohio)
)
County of Clermont)

Subscribed and sworn to before me this 8th day of December, 1995, by Victor Torbeck.

My commission expires:_____

/s/illegible
NOTARY PUBLIC